

REMARKS

This Amendment is submitted in follow-up to the personal interview conducted with Examiner Matthews on June 13, 2006 and also to the Office Action mailed on May 4, 2006. Claims 11, 13, 18, 19, 26, 28 and 29 have been amended. Claims 7, 8, 14-17, 20-25, 27 and 30-33 have been canceled. Claims 11-13, 18, 19, 26, 28 and 29 remain pending.

Supplemental Information Disclosure Statement

At the personal interview, the Examiner mentioned references of which he was aware that illustrated an adjustable annuloplasty ring. Subsequently, the Examiner gave the specific patent numbers to Applicants' undersigned counsel so that Applicants' undersigned counsel could also review the references. These references are submitted herewith in a Supplemental Information Disclosure Statement. Specifically, they are U.S. Patent Nos. 5,201,880; 5,306,296; and 5,674,279. Applicants respectfully submit that these references are no more relevant than the references of record when compared to the currently pending claims. Specifically, these references disclose mitral valve annuloplasty rings with anterior sections that may be moved upwardly in an adjustable fashion, for example, as shown in Fig. 3 of each of these patents. Thus, these references are no more relevant than the Cox and Sequin et al. references used by the Examiner to reject the claims in the most recent Office Action. As opposed to permanent upward bends or bows, these patents disclose movable or adjustable bends or bows in the anterior sections. As discussed at the interview, and discussed further below, such structures do not anticipate or suggest the subject matter set forth in Applicants' currently pending claims.

Interview Summary

Applicants and Applicants' counsel appreciate the courtesies extended by Examiner Matthews during the personal interview conducted on June 13, 2006. During that interview, Applicant, Dr. Paul A. Spence, showed the Examiner various models of devices consistent with the prior art being applied by the Examiner (i.e., showing an upward bend in the anterior portion of the device), and other models consistent with the embodiments disclosed in Figs. 23 and 24 of the present application. Dr. Spence also provided explanation as to how the figures in the present application accurately depict the various anatomical portions of the heart and, specifically, anterior and posterior portions of the mitral valve and corresponding portions of the annuloplasty devices. Proposed claim language changes were discussed with the Examiner as set forth in amended claim 11 submitted herewith and general arguments were presented, as also discussed below. The written description and drawings were agreed to be supplemented with reference numerals and accurate anatomical terminology and other material that is already shown in the drawings as originally filed. No new matter is being added by these changes.

As further evidence that the modifications to the drawings and specification do not add "new matter," but merely point out with reference numerals and words that which was already shown in the drawings and readily recognizable by one of ordinary skill, Dr. Spence has executed a Declaration under 37 CFR 1.132 attached herewith. At the end of the interview, the Examiner agreed that the Sequin and Cox references appeared to be overcome by the proposed claim language changes, including the change from "preformed" to "permanently formed" in claim 11. In this latter regard, the term "permanently formed" is meant to define over the Examiner's

interpretation of the Sequin and Cox references. As also discussed at the interview, the Sequin and Cox references do not show posterior sections that are permanently formed "to be nonplanar when viewed in a direction generally parallel to said first axis" and wherein the nonplanar generally curvilinear shape "is retained after fixation of the annuloplasty device to the valve annulus to improve coaptation of the leaflet free margins in the systolic configuration by fixing the annulus posterior portion into a non-planar configuration." Although the Examiner's interview summary form indicates that claims 7 and 8 would be amended to generally correspond to claim 11, Applicants have instead canceled claims 7 and 8, without prejudice, to simplify the issues in this application and expedite matters in this case.

Discussion of the Office Action

On page 2 of the Office Action mailed on May 4, 2006, the Examiner made various statements regarding Applicants' previous arguments. Applicants believe that this section of the Office Action is now moot in view of the amendment and, particularly, in view of the agreement reached in the interview to change "preformed" in claim 11 to "permanently formed."

On pages 3-4 of the Office Action, the Examiner rejected claims 7, 8 and 11-33 under 35 U.S.C. § 112, first paragraph. The Examiner made various more specific comments regarding terminology in the claims stating that the claims contained subject matter "which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Claims 7, 8, 14-17, 20-25, 27, and 30-33 have been canceled by way of this Amendment, without prejudice, in order to simplify the issues in this application. The remaining claims have been

amended, and the specification and drawings have been revised to provide clarification of the subject matter that was already inherently disclosed at least in the drawing figures, as viewed and understood by one of ordinary skill in the relevant art at the time the application was filed. With specific regard to the Examiner's comments on claim 28, the references to a "D"-shape are supported in Figs. 22 and 23, for example, and the text contained in the specification at the end of the paragraph beginning on page 24, line 12 has been added to describe that which was shown in the drawings upon filing. Applicants respectfully submit that the language contained in the currently pending claims is fully supported in the specification and drawings.

On page 4 of the Office Action, the Examiner rejected claim 18 under 35 U.S.C. § 101 stating that the posterior segment was positively recited in conjunction with the human body. That portion of claim 18 has been amended accordingly to eliminate the positive recitation and replace it with an intended-use recitation.

On page 5 of the Office Action, the Examiner rejected claims 7, 8 and 11-29 under 35 U.S.C. § 102(b) as being anticipated by Sequin et al., U.S. Patent No. 5,607,471. Specifically, the Examiner stated that Fig. 2 of the Sequin et al. patent discloses a ring "asymmetric about a minor axis perpendicular to a major axis" and further argued that the ring is "described as flexible and when implanted would inherently possess a segment extending downward relevant to another segment when implanted because the natural heart valve annulus is not planar and contracts." Among other claim changes, the only independent claim remaining, claim 11, has been amended to state that the posterior section has a "generally curvilinear shape, said generally curvilinear shape being permanently formed to be non-planar when viewed in a direction generally parallel to said first axis." The annuloplasty device is further

defined as "having a maximum width dimension along said first axis." Clearly, the Sequin et al. patent fails to disclose or suggest such a structure. As opposed to being "permanently formed" in the posterior section so as to be non-planar, the Sequin et al. reference, at most, is flexible and is not permanently formed into a non-planar configuration to fix the annulus posterior portion into a non-planar configuration. For at least these reasons, the rejection over Sequin et al. should be withdrawn.

On pages 5 and 6 of the Office Action, the Examiner also rejected claims 7, 8 and 11-31 under 35 U.S.C. § 102(e) as being anticipated by Cox, U.S. Patent No. 6,250,308. The Examiner specifically stated that Cox discloses a device in Figs. 2A and 2B having a "section bent out of plane." The Examiner further stated that "as the claims currently require, the major axis may be drawn about any elongated portion of the annuloplasty device." As discussed at the interview, the portion bent out of plane as shown in Figs. 2A and 2B of the Cox patent is the anterior section of the ring and not the posterior section of the ring as set forth in Applicants' claim 11. Moreover, the first axis as recited in claim 11 must be drawn to extend along the maximum dimension of the Cox device. Finally, the applied references and Applicants' claims must be interpreted consistent with how one of ordinary skill in the relevant art would interpret terms of art, such as "anterior" and "posterior." The curvature of the bow 70 shown in Fig. 2B of the Cox patent is specifically oriented upwards to conform "to the portion of the mitral valve annulus (34) that is located adjacent to the aortic valve root" (Cox, col. 5, lines 36-39). This is similar to the construction shown, for example, in Fig. 3 of the Sequin et al. patent discussed above, and is specifically located in the anterior section of the device, and not the posterior section of the device. Finally, the posterior section 15 of the Cox device is formed of a flexible material as discussed, for example, in

column 5, lines 26-32 of the Cox patent. Therefore, the additional language added to claim 11, as agreed to during the personal interview, also reads over any interpretation that a flexible posterior section anticipates or suggests a permanently formed non-planar posterior section. For at least these reasons, the rejection over Cox should be withdrawn.

Conclusion

Applicants respectfully submit that all outstanding objections, rejections and issues have been resolved and earnestly solicits a notice of allowance at this time.

If there is any additional matter in need of discussion upon review of this application, the Examiner is respectfully requested to contact Applicants' undersigned counsel by telephone to expedite issuance of this application.

Applicants believe that no fees are due in connection with this response. However, if such petition is due or any fees are necessary, the Commissioner may consider this to be a request for such and charge any necessary fees to deposit account 23-3000.

Respectfully submitted,

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